

STATISTICAL BRIEF

CARDIAC SURGERY AND PERCUTANEOUS CORONARY INTERVENTION SERVICES

This statistical brief is one of a series designed to provide data annually for monitoring the availability and utilization of certain health care resources in compliance with the Commission's State Health Plan for Facilities and Services. Under COMAR 10.24.17, existing providers of cardiac surgery and percutaneous coronary intervention services are to collect and report certain data; review conformance to standards for minimum volumes; and comply with the conditions of an approval, exemption, or waiver issued by the Commission. This brief includes the most recent annual data available from the specified sources.

Cardiac surgery refers to surgery on the heart or major blood vessels of the heart, including both open and closed heart surgery. Percutaneous coronary intervention (PCI) refers to a procedure whereby a catheter is inserted in a blood vessel and guided to the site of the narrowing of a coronary artery to relieve coronary narrowing. PCI procedures include both primary (emergency) and elective angioplasty.

To plan for cardiac services, MHCC has established four Regional Service Areas. The four Regions are:

Eastern Shore Region: Cecil, Kent, Queen Anne's, Caroline, Talbot, Dorchester, Wicomico, Worcester, and Somerset Counties.

Metropolitan Baltimore Region: Baltimore City and Carroll, Harford, Baltimore, Howard, and Anne Arundel Counties.

Metropolitan Washington Region: Washington, D.C. and Montgomery, Prince George's, Calvert, Charles, and St. Mary's Counties in Maryland.

Western Maryland Region: Garrett, Allegany, Washington, and Frederick Counties.

The Maryland Certificate of Need (CON) Program regulates non-federal hospitals in Maryland; a CON is required for the establishment of a new open heart surgery program. PCI procedures may be performed only in hospitals with on-site cardiac surgical backup, except as provided in the Commission's policies.

For cardiac surgery services, a large number of studies have demonstrated lower mortality rates for hospitals performing higher volumes of procedures. For elective PCI services, studies have also shown a greater incidence of complications and/or death in low volume programs as compared with high volume programs. The volume-outcome relationship has also been demonstrated in the limited data now available for primary PCI.

Based on this evidence, the Commission has established minimum volume requirements for cardiac services. There should be a minimum of 200 open heart surgery procedures performed annually in any institution in which open heart surgery is performed for adult patients.

Effective in 1997, a CON issued by the Commission for a new cardiac surgery program will require as a condition of issuance that the program achieve minimum volume standards within 24 months of beginning operation and maintain a level of utilization at or above the minimum volume in each subsequent year of operation.

Over the past decade, initiatives designed to support improvements in the quality of cardiac services have emphasized measurement and reporting of outcomes (such as in-hospital mortality) as well as improving the processes of care (for example, increasing adherence to clinical practice guidelines). The Commission has established an advisory committee to recommend strategies for developing an ongoing, statewide program to improve the quality of cardiovascular care in Maryland.

CARDIAC SURGERY

Open heart surgery (OHS) means cardiac surgery during which a heart-lung machine (i.e., cardiopulmonary bypass or CPB) may temporarily assume the functions of the patient's heart and lungs. Minimally invasive procedures that do not require the use of CPB support are also included. (In the discharge abstracts, additional coding is required to identify extracorporeal circulation (CPB) auxiliary to open heart surgery.)

There are currently nine Maryland hospitals performing cardiac surgery and elective PCI services. In addition, there are currently three Washington, D.C. hospitals that the Commission considers in its Metropolitan Washington planning region for cardiac surgery.

In 2002, three hospitals in the Metropolitan Washington Region performed fewer than the minimum volume of 200 open heart surgery procedures.

Adult Open Heart Surgery Cases: Maryland and Washington, D.C. Hospitals, 2000-2002.

Region/Facility	2000	2001	2002
Western Maryland Region			
Sacred Heart Hospital*	26	242	285
Metropolitan Washington Region			
Prince George's Hospital Center	155	150	159
Washington Adventist Hospital	802	770	739
<i>Total Maryland</i>	<i>957</i>	<i>920</i>	<i>898</i>
Georgetown University Hospital†	122	269	260
George Washington Univ Hospital	103	177	190
Howard University Hospital	45	20	23
Washington Hospital Center	2,631	2,324	2,252
<i>Total Washington, D.C.</i>	<i>2,901</i>	<i>2,790</i>	<i>2,725</i>
<i>Metropolitan Washington Total</i>	3,858	3,710	3,623
Metropolitan Baltimore Region			
St Joseph Medical Center	1,388	1,226	1,181
Johns Hopkins Hospital	1,023	1,063	946
Sinai Hospital	547	544	522
Union Memorial Hospital	1,034	1,074	938
University of Maryland Med Ctr	521	427	490
<i>Metropolitan Baltimore Total</i>	4,513	4,334	4,077
Eastern Shore Region			
Peninsula Regional Med Ctr	658	650	673
Total	9,055	8,936	8,658

Source: Maryland Hospital Discharge Abstracts 2000 (file created 3/27/2001), 2001 (file created 6/3/2003), 2002 (file created 6/6/2003).

DC Hospital Discharge Abstracts 2000, 2001, 2002.

* Sacred Heart Hospital performed its first OHS procedure on 11/13/2000.

† Georgetown University Hospital consolidated its OHS program with Washington Hospital Center on August 1, 2003.

PERCUTANEOUS CORONARY INTERVENTION

Improvements in the technique of angioplasty or percutaneous coronary intervention coupled with expanded indications have increased the number of patients receiving this therapy over the past decade. There are generally two types of angioplasty procedures. While the large majority of angioplasty procedures are performed as elective procedures, angioplasty is also used as a primary means of urgent revascularization in the treatment of certain patients with acute ST-segment elevation myocardial infarction (MI).

The 'ST-segment' is one part of the electrical wave of the heart recorded by the electrocardiogram (ECG). The ECG measures the electrical activity of the heart. The electrical wave that is caused by the heart's activity is composed of several parts. Changes in the electrical wave or one of its parts can define different types of heart attacks (or myocardial infarctions). When the ST-segment is higher than (or elevated above) normal, that signals a type of heart attack that can be treated with clot busting drugs (thrombolytic therapy) or primary angioplasty.¹

When PCI is used to treat certain acute MI patients, rather than thrombolytic therapy, the procedure is referred to as primary PCI. Primary PCI procedures comprise a relatively small number in comparison to elective procedures. (In the discharge abstracts, primary angioplasty is not specifically identifiable in the procedural coding.)

¹ Thomas Aversano, M.D., C-PORT Medical Director.

Adult PCI Cases: Maryland and Washington, D.C. Cardiac Surgery Hospitals, 2000-2002.

Region/Facility	2000	2001	2002
Western Maryland Region			
Sacred Heart Hospital	-	211	420
Metropolitan Washington Region			
Prince George's Hospital Center	445	466	460
Washington Adventist Hospital	1,696	1,685	1,908
<i>Total Maryland</i>	<i>2,141</i>	<i>2,151</i>	<i>2,368</i>
Georgetown University Hospital	159	296	297
George Washington Univ Hospital	188	321	453
Howard University Hospital	40	49	72
Washington Hospital Center	3,640	3,645	3,421
<i>Total Washington, D.C.</i>	<i>4,027</i>	<i>4,311</i>	<i>4,243</i>
<i>Metropolitan Washington Total</i>	6,168	6,462	6,611
Metropolitan Baltimore Region			
St Joseph Medical Center	2,037	2,234	2,581
Johns Hopkins Hospital	1,245	1,400	1,278
Sinai Hospital	1,111	1,147	1,222
Union Memorial Hospital	1,384	1,550	1,731
University of Maryland Med Ctr	556	503	416
<i>Metropolitan Baltimore Total</i>	6,333	6,834	7,228
Eastern Shore Region			
Peninsula Regional Med Ctr	1,629	1,498	1,484
Total	14,130	15,005	15,743

PCI procedures were identified as any procedure, principal or other, with ICD-9-CM codes of 36.01, 36.02, or 36.05.

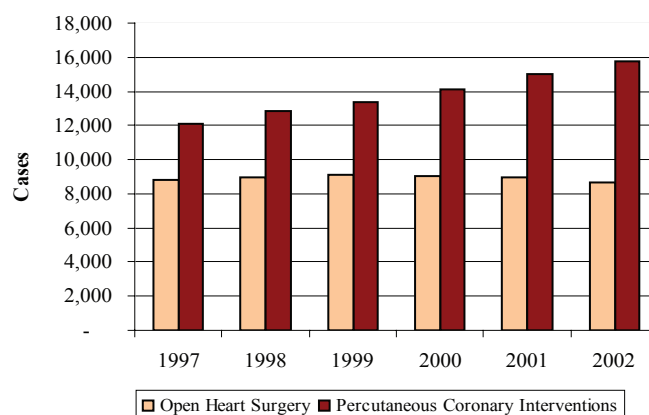
Source: Maryland Hospital Discharge Abstracts 2000 (file created 3/27/2001), 2001 (file created 6/3/2003), 2002 (file created 6/6/2003).

DC Hospital Discharge Abstracts 2000, 2001, 2002.

In 2002, one hospital in the Metropolitan Washington Region performed fewer than the recommended minimum volume of 200 elective PCI procedures.²

The total number of PCI procedures at cardiac surgery hospitals in Maryland and Washington, D.C. increased by 3,649 cases from 1997 to 2002 (30 percent, or, on average, six percent per year). Over the same six-year period, the number of open heart surgery cases decreased by 176 cases (2 percent, or, on average, 0.4 percent per year).

Adult Open Heart Surgery and PCI Cases: Maryland and Washington, D.C. Cardiac Surgery Hospitals, 1997-2002.



Maryland Hospital Discharge Abstracts 1997-2002.
DC Hospital Discharge Abstracts 1997-2002.

² Smith SC, Jr, Dove JT, Jacobs AK, Kennedy JW, Kereiakes D, Kern MJ, Kuntz RE, Popma JJ, Schaff HV, Williams DO. ACC/AHA Guidelines for Percutaneous Coronary Intervention: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. *JACC*, Vol. 37, No. 8, June 15, 2001:1-66.

In April 2003, the U.S. Food and Drug Administration (FDA) approved a drug-eluting stent for angioplasty procedures. The stent is coated with a drug and gradually releases it into the wall of the coronary artery. Previously, the long-term benefits of PCI were limited by the occurrence of restenosis (15-30 percent); however, in some studies, drug-eluting stents reduced restenosis to close to 0 percent. It is unclear what the short- and long-term consequences of this advance will be on cardiac surgical volume. It is anticipated that interventional cardiologists will experience an increase in volumes, as the new stents accommodate some patients previously scheduled for open heart surgery. While bypass procedures may decline initially, analysts expect cardiac surgeons to continue to be busy because the stents do not cure heart disease, but only lengthen the time without recurrence of symptoms.³ After receiving a number of reports of adverse events, the FDA issued two notifications, in July and October 2003, to physicians about appropriate use of the stents.⁴

PCI Waivers

State health planning policy requires that angioplasty procedures be performed only in hospitals with on-site cardiac surgical backup; however, the Commission may waive its policy if the exemption meets specific conditions.

C-PORT Hospitals

Currently, the State Health Plan exemption for research proposals permits hospitals without on-site cardiac surgery backup to perform primary (emergency) angioplasty for patients with acute ST-segment elevation myocardial infarction under the protocols of the Cardiovascular Patient Outcomes Research Team (C-PORT) project. The research team initiated the project with six Maryland hospitals participating in a study to evaluate the safety and efficacy of providing primary angioplasty in hospitals without on-site cardiac surgery versus thrombolytic therapy for the treatment of acute myocardial infarction. (The trial also included hospitals in Massachusetts.)

From 1996 to 1999, the C-PORT project enrolled patients in a randomized, clinical trial. The data from this study made an important contribution to the knowledge base concerning whether primary angioplasty services can be provided safely by hospitals without on-site cardiac surgery programs.⁵ In its second phase, which began in August 1999, the C-PORT project is functioning as a registry.

One of the six hospitals that participated in the randomized trial ended its participation in 1998; in 1999, the C-PORT Primary PCI Registry started with three hospitals, including two that had participated in the trial. Recent data from the registry show that from 2000 to 2002 the number of hospitals increased by 50 percent (6 to 9) statewide, while the number of procedures increased by 280, or 130 percent. (Discharge abstract data reported by the participating hospitals generally show fewer procedures per year, ranging from a difference of one to 21 procedures.) To date, the number of registry participants has increased to 11 hospitals.

Primary PCI Cases: Maryland C-PORT Hospitals, 2000-2002.

Region/Facility	2000	2001	2002
Metropolitan Washington Region			
Holy Cross Hospital (1)	26	55	68
Shady Grove Adventist Hospital (2)	10	68	76
Suburban Hospital	48	38	72
Southern Maryland Hospital Center (3)	-	-	57
<i>Metropolitan Washington Total</i>	84	161	273
Metropolitan Baltimore Region			
Anne Arundel Medical Center (4)	-	-	22
Johns Hopkins Bayview Medical Ctr (5)	78	70	50
St. Agnes Hospital	46	113	97
North Arundel Hospital (6)	-	30	48
<i>Metropolitan Baltimore Total</i>	124	213	217
Eastern Shore Region			
Memorial Hospital at Easton	8	5	6
Total	216	379	496

Source: Thomas Aversano, M.D., C-PORT Medical Director.

- (1) Holy Cross Hospital commenced primary angioplasty procedures in the C-PORT registry on 07/12/2000.
- (2) Shady Grove Adventist Hospital commenced primary angioplasty procedures in the C-PORT registry on 09/29/2000.
- (3) Southern Maryland Hospital Center commenced primary angioplasty procedures in the C-PORT registry on 01/29/2002.
- (4) Anne Arundel Medical Center commenced primary angioplasty procedures in the C-PORT registry on 10/15/2002.
- (5) Johns Hopkins Bayview Medical Center commenced primary angioplasty procedures in the C-PORT registry on 3/02/2000.
- (6) North Arundel Hospital commenced primary angioplasty procedures in the C-PORT registry on 02/14/2001.

Franklin Square Hospital Center commenced participation in the C-PORT registry, with its first procedure performed on May 3, 2003. Howard County General Hospital commenced participation in the C-PORT registry, with its first procedure performed on September 6, 2003.

Although there remain important questions on the role of primary angioplasty in treating acute MI, this therapy has gained widespread acceptance among cardiologists as the preferred approach for treating acute ST-segment elevation MI when it can be performed rapidly and in an environment that has the necessary institutional and health care professional resources. The superiority of primary PCI when compared to thrombolytic therapy for the treatment of acute ST-segment elevation MI has been demonstrated in a large number of studies.

³ Mike Norbut. New stents pricey, yet a cost-saver. *American Medical News*, Vol 46, No 19, 2003.

⁴ FDA Public Health Web Notification: Information for Physicians on Sub-acute Thromboses (SAT) and Hypersensitivity Reactions with Use of the Cordis CYPHER™ Coronary Stent, Issued 10/29/2003.

⁵ Aversano T, Aversano LT, Passamani E, Knatterud GL, Terrin ML, Williams DO, Forman SA; Atlantic Cardiovascular Patient Outcomes Research Team (C-PORT). Thrombolytic therapy vs primary percutaneous coronary intervention for myocardial infarction in patients presenting to hospitals without on-site cardiac surgery: a randomized controlled trial. *JAMA*. Vol. 287, No. 15. Apr 17, 2002: 1943-1951.

